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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,841	03/01/2002	Martin Caldwell	1890-0020	1503

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EXAMINER

THALER, MICHAEL H

ART UNIT PAPER NUMBER

3731

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,841

Applicant(s)

CALDWELL ET AL.

Examiner

Michael Thaler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2, 11-12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the external proximal valve defined in claims 9, 11 and 12 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claims 3-5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The description of the valve 8 shown in figures 2 and 3 (page 5, lines 5-19 of the specification) is so confusing and unclear that it would not enable one skilled in the art to make and/or use the invention. For example, it is unclear exactly what the "actuators" are. Further, the shape and location of the "actuators" is unclear. It is unclear where the "a distal tube" (page 5, lines 8-9) is.

Claims 3-5, 10, 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

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regards as the invention. The scope of claims 3-5 is unclear for the reasons set forth in the paragraph above. Claim 10 contradicts claim 9 (from which it depends) since the valve may not be both an external proximal valve and also an internal distal valve. In claim 11, line 9, "connectable" should be "connected" since the sleeve is not removable from the body cavity engagement means and the fixing means.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Golub et al. (5,514,133). Golub et al. disclose body cavity engagement means (distal ring 14), fixing means (proximal ring 12), sleeve 16 having an associated connector ring 56 for receiving medical instruments (passing within the apparatus 10) and sealing means 62, 64. The Golub et al. specification fails to specifically indicate that the sealing means 62, 64 mould about a substantial portion of a surgeon's hand or surgical instrument.

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However, it would have been obvious that this occurs to some extent since figure 5 shows the flap valve seals tightly engaging the surgeon's arm and since flap valve seals typically are very flexible. Alternatively, it would have been obvious that the "envelope seals" described in col. 5, lines 8-10 mould about a substantial portion of a surgeon's hand or surgical instrument since envelope seals, by definition, envelope (or mould about) the object passing within them. Note that the sleeve 16 is inherently adjustable by the positioning of the proximal ring 12 since, once the adjustment members 24 are anchored to the proximal ring (as indicated in col. 5, lines 29-320), pulling the proximal ring upwards will cause the sleeve 16 to also be pulled upwards to even further tighten the seal between the incision and sleeve. Alternatively, rotating the proximal ring will inherently twist sleeve 16 and thereby shorten it. Thus, Golub et al. discloses the adjustment means for adjusting or modifying the length of the sleeve defined in claims 7 and 12. However, assuming *arguendo* that Golub et al. fails to disclose adjustment means for adjusting the length of the sleeve, as defined by 35 U.S.C. 112, sixth paragraph, since Golub et al. fails to disclose the step of using the device in this manner, it was well known to rotate a proximal ring of a surgical port in order to twist and tighten an attached sleeve

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which passes through the incision in order to insure that a good seal is formed between the incision and the sleeve. It would have been obvious to so use the Golub et al. device so that it too would have this advantage. As to claim 8, The Golub et al. fails to disclose that sleeve 16 (bellows 54) is made of elastomer material. However, it was well known that bellows typically are formed of elastomer material so that they return to the original shape when unstressed. It would have been obvious to form bellows 54 of elastomer material so that it too would have this advantage. As to claim 10, the Golub et al. valve 62, 64 is an internal distal valve, as broadly claimed since it is internal of the apparatus 10 and distal to proximal member 56. Alternatively, it was well known to locate the valve of a surgical port distally within the incision with the advantage that it insures that no fluid can escape into the port. It would have been obvious to so locate the Golub et al. valve so that it too would have this advantage.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

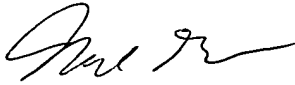
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be

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reached on (703)308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht
September 25, 2003


MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731